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GUIDANT

JUN 15 2006

Appendix A
510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Guidant Corporation
Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95052
Telephone: **Fax**:	951-914-4412 951-914-0214
Contact Person:	Mara Caler
Date Prepared:	March 23, 2006
Device Trade Name:	OMNILINK® .018 Biliary Stent System
Device Common Name:	Biliary Stent
Device Classification Name:	Biliary Catheter
Device Classification:	Class II

Summary of Substantial Equivalence:

The OMNILINK® .018 Biliary Stent System, subject device of this 510(k), is substantially similar in materials, design and intended use to the predicate devices, OTW MEGALINK® SDS Biliary Stent System (K992319), and the OMNILINK® .018 Biliary Stent System (K011039 and K033834). The changes described herein involve optimized manufacturing parameters, revised test methods, addition of process monitoring, updates to the product labeling and related updates to the product specification.

Device Description:

The OMNILINK® .018 Biliary Stent System is a balloon-expandable stent composed of 316L medical grade stainless steel. The stent is pre-mounted onto an over-the-wire (OTW) delivery catheter.

The OMNILINK® .018 Biliary Stent System consists of a dual stent design, fabricated from a single piece of 316L medical grade stainless steel tubing. The stent designs are based on a series of zigzagging rings with multiple articulations per ring. The stents are available in two designs which primarily differ in strut width and the length of the basic cell. One design is used for stent sizes 5.0mm – 7.0mm and the other for stent sizes 8.0mm – 10.0mm.

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The delivery system is an over-the-wire, co-axial design with a balloon at the distal end. The delivery catheter's central lumen is designed to permit the use of a 0.018" guide wire to facilitate advancement of the catheter to and through the stricture to be dilated. Once the delivery system is placed in the desired location, the stent expands upon inflating the balloon with contrast medium. The balloon provides an expandable segment of known diameter and length at specific pressures. In addition, the balloon has two radiopaque markers to aid in stent positioning. The stent is designed to remain in the biliary duct as a permanent implant.

The subject device OMNILINK® .018 Biliary Stent System consists of stent sizes of diameters ranging from 5.0mm – 10.0mm with stent lengths of 18, 28, 38, 58mm and delivery system length of 80 and 135cm. The stent and delivery system are supplied sterile and is intended for single use only.

Intended Use:

The OMNILINK® .018 Biliary Stent System is indicated for palliation of malignant strictures in the biliary tree.

Technological Characteristics:

Similar to the predicate devices, the subject device OMNILINK® .018 Biliary Stent System is comprised of a 316L stainless steel balloon-expandable stent pre-mounted onto an over-the-wire, co-axial design delivery catheter with a balloon bonded at the distal end. The catheter shaft with a co-axial lumen provides a conduit for contrast medium to inflate the balloon. Upon balloon inflation with contrast medium, the stent expands to a specific diameter. The stent is a permanent implant. The system is designed for single use.

Performance Data:

No performance standards have been established for Biliary Stents under Section 514 of the Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mara Caler
Regulatory Affairs
Guidant Corporation
26531 Ynez Road
TEMECULA CA 92591

JUN 15 2006

Re: K060817
Trade/Device Name: Guidant OMNILINK® .018 Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: May 1, 2006
Received: May 4, 2006

Dear Ms. Caler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> This device is not intended for any vascular indications. The safety and effectiveness of this device for use in the vascular system has not been established and could result in serious harm and/or death.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

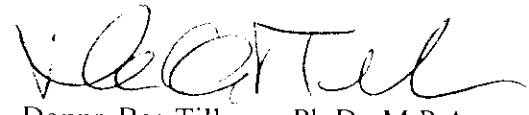
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K060817

Device Name: Guidant OMNILINK® .018 Biliary Stent System

FDA's Statement of the Indications For Use for device:

The Guidant OMNILINK® .018 Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, ... Renal,
and Radiological Devices
510(k) Number K060817